

Memorandum

Date: 15 November 1983

Subject: EPA Reg. No. 270-174 NATURE'S OWN HERBAL FLEA REPELLENT COLLAR
Caswell #618, 618A,
In 10-27-83; Record No. 107921

From: B. T. Backus
IRB/TSS

To: Mr. Tim Gardner
Product Manager 17

Registrant: Farnham Companies, Inc
2230 E. Magnolia St.
Phoenix, AZ 85031

Active Ingredients:

Oil of Citronella.....	0.50%
Oil of Eucalyptus.....	1.00%
Oil of Cedar.....	0.50%
Oil of Pennyroyal.....	2.00%
Inert Ingredients:.....	96.00%

Background:

This collar is currently registered for use on dogs only. The registrant is proposing to amend the label to allow use on cats. Oral LD₅₀, a combination dermal LD₅₀/irritation, and primary eye irritation studies have been submitted. The registrant is proposing a one month collar study on cats to observe whether dermal sensitization/irritation occurs.

Comments and Recommendations:

1. The acute oral LD₅₀, combination dermal LD₅₀/irritation, and eye irritation studies received 10-3-83 are acceptable.
2. The cat collar irritation/sensitization study, as outlined, would probably be classified as supplementary data after review. We consider the Landsteiner protocol (or some modification), with male guinea pigs as subjects, more conclusive in determining whether or not a sensitization potential exists.

Review:

The following studies were conducted on a formulation made up of the active ingredients, in the percentage which they occur in the collar, plus 0.125% oil of rue, with the remainder of the formulation being corn oil. These studies were conducted at Cosmopolitan Safety Evaluation, Inc. P.O. Box 71, Lafayette, NJ 07848. Studies were received at EPA 10-03-83, and are in Acc. 251420.

1. Acute Oral LD₅₀ - rat. Study #0646A, dated 1 Feb. 1983.

Procedure: 5M, 5F SD rats received an oral dosage of 5 g/kg of test material, with subsequent 14-day observation.

Results: No mortalities. One female reported to have had diarrhea at 3 hrs, ascribed to corn oil. Reported that at post-sacrifice necropsies no gross abnormalities were observed. Oral LD₅₀ > 5 g/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

2. Primary Eye Irritation - rabbit. Study #0646D, dated 1 February 1983.

Procedure: 0.1 ml was placed in one eye of each of 9 rabbits. Three eyes were flushed with water for one minute, starting no sooner than 30 seconds after instillation.

Results: Only sign of irritation was slight conjunctival redness of some eyes at 24 hrs. All eyes clear by 48 hrs.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

The following study was conducted using strips of collar.

3. Acute dermal LD₅₀ and primary dermal irritation - rabbit. Study #0646B; dated 1 February 1983.

Procedure: Each of 5M, 5F NZ albino rabbits received a 24-hr occluded dermal exposure to 4 collar strips (dosage level > 2 g/kg), with subsequent 14-day observation.

Results: Reported that there was no mortality, no irritation.

Study Classification: Core Minimum Data (not reported whether test material was moistened with physiological saline solution) both as a dermal LD₅₀ and primary dermal irritation study.

Product Classification: Tox. Cat. III (dermal LD₅₀)
Tox. Cat. IV (primary dermal irritation).

Byron T Backus 11-15-83

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